510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K041240

B. Analyte:
Sperm count quality control

C. Type of Test:
Semen analysis sperm count, manual, semi automated, or automated

D. Applicant:
Fertility Solutions, Inc.

E. Proprietary and Established Names:
AQC™ Sperm Count Quality Control, AQC™ Post-Vasectomy Quality Control, AQC™ Sperm Count Proficiency Challenge, AQC™ Post-Vasectomy Proficiency Challenge

F. Regulatory Information:

1. Regulation section:
   21 CFR 864.8625 Hematology Quality Control Mixture
2. Classification:
   Class II
3. Product Code:
   NRF
4. Panel:
   Hematology (81)

G. Intended Use:

1. Indication(s) for use:
   The AQC™ Sperm Count and AQC™ Post-Vasectomy Quality Controls are intended for monitoring sperm counts performed either manually using commercially available counting chambers or using computer assisted semen analysis (CASA) instruments. The AQC™ Sperm Count and AQC™ Post-Vasectomy Quality Controls are intended for use as quality control materials having known sperm concentrations. Daily monitoring of the control values establishes intra-laboratory parameters for accuracy and precision of the cell counting methods. These products are also available for external laboratory quality control and proficiency testing and as such are sold under the proprietary trade names AQC™ Sperm Count and AQC™ Post-Vasectomy Proficiency Challenges.

2. Special condition for use statement(s):
   N/A

3. Special instrument Requirements:
   N/A

H. Device Description:

These devices employ a liquid human semen matrix and a stabilized human sperm cell constituent formulation. Each two level control is a ready-to-use liquid requiring no reconstitution or dilution. Preservatives including formalin have been added to inhibit microbial growth. The AQC Sperm Count and AQC Post-Vasectomy Quality Controls are identical to the AQC Sperm Count and AQC Post-Vasectomy Proficiency Challenges except for the volume.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   a. Streck Laboratories, Para Tech Plus Retics (K993825)
   b. Quantimetrix Corp., Synovialscopics Control (K010598)
   c. R & D Systems, Inc. R & D Body Fluid Control (K020229)
   d. R & D Systems, Inc. R & D Hematology Control (K010409)
2. Predicate K number(s):
   See above.
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	QC material for cell counts	Same
Form	Liquid suspension containing stabilized human cells	Same for a, b, and c above in I. 1.
Differences		
Item	**Device**	**Predicate**
Matrix	Human spermatozoa	Human white blood cells and red cells
Form	Liquid suspension containing stabilized human cells.	d. above contains mammalian white blood cells and platelets in addition to human white blood cells and red cells.
Levels of control	Two	a. has one level; b and c have two levels; and d has three levels

J. Standard/Guidance Document Referenced (if applicable):

Points to Consider for Hematology Quality Control Materials, OIVD, September 30, 1997.

K. Test Principle:

N/A

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. *Precision/Reproducibility:*
    N/A
    b. *Linearity/assay reportable range:*
    N/A
    c. *Traceability (controls, calibrators, or method):*
    N/A
    d. *Detection limit:*
    N/A
    e. *Analytical specificity:*
    N/A
    f. *Assay cut-off:*
    N/A
2. Comparison studies:
    a. *Method comparison with predicate device:*
    N/A
    b. *Matrix comparison:*
    N/A
3. Clinical studies:
    a. *Clinical sensitivity:*
    N/A
    b. *Clinical specificity:*
    N/A
    c. *Other clinical supportive data (when a and b are not applicable):*

4. Clinical cut-off:
    N/A
5. Expected values/Reference range:
    Representative values as per "Points to Consider" document:
    a. Sperm Count Level One=0-30 million / mL
    b. Sperm Count Level Two= 30-75 million / mL
    c. Post-Vasectomy Negative (absence of sperm)=0 sperm present
    d. Post-Vasectomy Positive (presence of sperm)= 0.5-2.0 million / mL

M. Conclusion:

The Fertility Solutions, Inc. AQC Sperm Quality Controls and AQC Post-Vasectomy Quality Controls are substantially equivalent to the predicate devices.